510 (k) Summary

Submitter's information:

Name:	LeMaitre Vascular, Inc.
Address:	63 Second Avenue Burlington, MA USA 01803
Phone:	781-425-1727
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Contact Person:	Bryan Cowell, MSc., RAC

NOV 0 6 2013

Date of preparation:	June 24, 2013
Device Name:	LeMaitre 8F Occlusion Catheter
Trade Name.	LeMaitre 8F Occlusion Catheter
Common/ Classification Name:	Catheter, intravascular occluding, temporary
Classification Panel:	21CFR §870.4450
Class:	II (2)
Product Code:	MJN

Establishment Registration: 1220948

Establishment: LeMaitre Vascular, Inc., 63 Second Avenue, Burlington, MA USA 01803

Owner/Operator: 1220948

Device Description:

The 8F Occlusion Catheters is offered in two balloon sizes; 28 mm or 45mm. It is a single lumen catheter with a latex balloon specifically designed and sized for use in the outlined general procedures. The single lumen (inflation lumen indicated by the white stopcock) is used for balloon inflation. The stop-cock is to maintain balloon inflation level throughout the procedure. The device has radiopaque marker bands at the proximal and distal ends of the balloon to enhance visibility of the balloon location when used under fluoroscopy.

Intended Use:

The LeMaitre 8F Occlusion Catheter is indicated for temporary vessel occlusion.

Predicate Device:

510(k):	K093911
Device Name:	Fogarty Occlusion Catheter

Substantial Equivalence:

Fundamental Scientific Technological Characteristics:

The LeMaitre 8F Occlusion Catheter maintains the same intended use and fundamental scientific technology as the predicate device.

Functional/ Safety testing:

The verification activities conducted indicate that LeMaitre 8F Occlusion Catheter device meets the product performance requirements of the device specifications and does not raise any additional safety issues.

Sterilization:

The device is validated for ethylene oxide (EO) sterilization according to ANSI/AAMI/ISO 11135-1:2007, "Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization".

Biocompatibility:

All blood contact portions of the device were subjected to biocompatibility testing according to ISO 10993 guidelines for an externally communicating device with limited contact duration (<24 hours), with circulating blood. The biocompatibility assessment established that 8F Occlusion Catheter is biocompatible.

Summary of Product Testing:

The following tests have been completed to evaluate the safety and performance of LeMaitre 8F occlusion catheter compared with the predicate device:

- Volume Required to Inflate Balloon to IFU Indicated Diameter
- Inflation Pressure
- Radial Force
- Contact Area
- Inflation Time
- Deflation Time
- Burst Volume

Conclusion:
LeMaitre Vascular has demonstrated that the LeMaitre 8F Occlusion Catheter is substantially equivalent to the predicate device based on its intended use and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 6, 2013

LeMaitre Vascular, Inc.
c/o Mr. Xiang (Vic) Zhang
Director of Regulatory Affairs
63 Second Ave.
Burlington, MA 01803

Re: K132022
Trade/Device Name: LeMaitre 8F Occlusion Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: October 22, 2013
Received: October 29, 2013

Dear Mr. Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K132022/S002

Device Name LeMaitre 8F Occlusion Catheter.

Indications for Use LeMaitre 8F Occlusion Catheter is indicated for temporary vessel occlusion.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___X___ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

Bram D. Zuckerman -S